K011258

MAY 24 2001

APPENDIX V

SUMMARY
OF
SAFETY AND EFFECTIVENESS INFORMATION

K011258

510(k) Summary of Safety and Effectiveness

[in accordance with SMDA of 1990, 21 CFR 807.92(c)]

Contact: Mr. Hartmut Loch, RAC
Director, Regulatory Affairs
PLUS ORTHOPEDICS
6055 Lusk Blvd.
San Diego, CA 92121-2700
Tel: 858.550.3800

Trade Name: TC-PLUS™ Porous Femoral Components

Common Name: Cemented Knee Prosthesis

Classification Name: Prosthesis Knee, Patelllofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer

Classification Number: 21 CFR 888.3560

Device Class: Class II

Classification Panel: 87 Orthopedic Devices Panel

Product Code: JWH

Predicate Device: TC-PLUS® Solution Knee System, which was cleared for marketing in the U.S.A. by FDA (K000666 S/E 10/13/2000) and is also manufactured by PLUS Endoprothetik AG, Switzerland

Device Modification Description: The TC-PLUS™ Porous Femoral Components are identical to the predicate device, except that they are Ti-Plasma coated on the underside. They are identical in indications for use, geometry, material, and surface characteristics to the predicate device, and they are intended for use only with bone cement. These additional porous coated femoral components are available in right and left, sizes 2, 4, 6, 8, 10, and 12.

The tibial components as well as the tibial PE inserts have not been changed and are identical to the predicate device.

Indications:	The TC-PLUS™ Porous Femoral Component is intended as a cemented surface replacement in treating patients who are candidates for primary total knee arthroplasty or revision knee arthroplasty. It is indicated for degenerative, post-traumatic or rheumatoid arthritis, avascular necrosis of the femoral condyle, post-traumatic loss of joint configuration, in particular in the event of patello-femoral erosion, functional disability or an earlier patellectomy; moderate varus, valgus or flexure deformity and to correct earlier unsuccessful attempts at surgery.
Contraindications:	Contraindications include acute or chronic infections (local or systemic), serious lesions of muscles, nerves or blood vessels, which put the affected limb at risk, bony defects or poor bone quality, which might endanger the stability of the prosthesis, and any concurrent disease, which might interfere with the function of the implant.
Performance data:	Biomechanical tests have been performed. The test results are included in this submission and show that the additional components were equivalent to the predicate device and are sufficient for in vivo loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 24 2001

Mr. Hartmut Loch
Director, Regulatory Affairs
Plus Orthopedics
6055 Lusk Boulevard
San Diego, California 92121

Re: K011258
Trade Name: TC-PLUS™ Porous Femoral Component
Regulation Number: 888.3560
Regulatory Class: II
Product Code: JWH
Dated: April 23, 2001
Received: April 24, 2001

Dear Mr. Loch:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: k011258

Device Name(s):

TC-PLUS™ Porous Femoral Components

Indications for Use:

The TC-PLUS™ Porous Femoral Component is intended as a cemented surface replacement in treating patients who are candidates for primary total knee arthroplasty or revision knee arthroplasty. It is indicated for degenerative, post-traumatic or rheumatoid arthritis, avascular necrosis of the femoral condyle, post-traumatic loss of joint configuration, in particular in the event of patello-femoral erosion, functional disability or an earlier patellectomy; moderate varus, valgus or flexure deformity and to correct earlier unsuccessful attempts at surgery.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number 011258

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional format 1-2-96)